Exhibit FF

From: Jason Herzog </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E33558535709468682 3CD25492F9F4D6-JHERZOG>
To: Dominique Delagnes; Michele Glinn
Sent: 8/11/2022 8:00:39 PM
Subject: Klette Audit
Attachments: _MICHIGAN CONTRACT INFORMATION.docx

Dominique and Michele,
Kevin would like to come on site for three days next week to review 150 samples. Specifically, he would like to review 100 positive sampled and about 50 PT samples. He would like us to organize the information in the following manner. Can we accommodate this request (recognize the MRO request does not apply)?

1. The drug test positive results to be audited will be selected from a spreadsheet provided by Averhealth. Assemble the following specimen records in the order reflected on the spreadsheet.

· A copy of all reports sent to the MRO (CCF, hard copies of electronic reports if used).

· All chain of custody documentation (specimen and aliquot) for receipt, testing, and storage.

· Initial test data, initial and confirmatory SVT data /results, and confirmatory drug test data supporting the specimens reported results (including data for calibrators, controls, and other specimens in the batch).

· All associated internal documents (e.g., review sheets, and checklist).

2. Organize these records to facilitate their review and provide all of them to the auditor at the beginning of the audit.

· Specimen records must be organized in the order reflected on the spreadsheet.

· All records for a specimen should be clearly linked to facilitate retrieval and review of all records associated with each selected specimen.

Many thanks,
Jason

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MICHIGAN CONTRACT INFORMATION (required prior to the inspection audit)

Question	Owner	Status	Response
1. What is the purpose of testing for specimens submitted under the contract for the state of Michigan (e.g., random testing, preemployment, Accident Investigation, or criminal drug monitoring?	Jason	Complete.	Child protective services. Test results are used when placing children with guardians and when parent/guardians are suspected of abuse or neglect associated with substance use.
2. Does the lab perform both screening and confirmation testing per the contract with Michigan?	Jason	Complete.	From contract inception to December 2020, all oral fluid samples were direct to LCMS because the cutoff levels were too low for screening. On the counsel of Averhealth, MDHHS agreed to increase cutoff levels to industry standards and since all samples are initially screened and positive screens are confirmed via LCMS.
3. What are the drug analytes for the panel of drugs required for the contract with Michigan?	Courtney	Complete.	
4. Does the laboratory perform specimen validity testing for the Michigan contract?	Jason	Complete.	Validity testing is conducted via creatinine for urine samples, which represents less than 5% of samples. Nearly all other samples are oral fluid.
5. What are the cut-off levels for the panel of drugs for each analyte tested for per the Michigan contract?	Jason	Complete.	See supporting documents referring the cutoff levels pre and post 11.30.2020.
6. What instrument does the lab use to screen the specimens for the Michigan contract?	Jason	Complete.	Oral Fluid Screening: AU800 Urine Screening: AU8400 Confirmation: AbSciex 4500 triple quadrupole coupled with a Shimadzu liquid chromatograph.
7. What instrument does the lab use to confirm positive specimens for the Michigan contract?	Jason		AbSciex 4500 triple quadrupole coupled with a Shimadzu liquid chromatograph.
8. How is the confirmation instrument calibrated for the testing of specimens under the Michigan contract?	Michele	Complete	Calibrators and controls are run with each batch. Concentrations and acceptable performance standards are listed in each SOP.

9. Are the specimens received under the Michigan contract previously screened by another laboratory before arriving at Averhealth?	Jason	Complete.	No.

ANALYSIS INFORMATION (required prior to the inspection audit)

Question	Owner	Status	Response
1. What Quality Control specimens (QCs) and their concentrations are prepared and required in each confirmation batch?	Michele	Complete	Each confirmation batch has a negative, low, mid and high-concentration control. Concentrations span the calibration range. A set is run after the calibrators and again after every 40 samples and/or at the end of the batch. Urine batches may also have glucuronide controls, and hair batches have extracted controls as well. Specific concentrations are listed in each of the assay procedures.
2. What are the percentage of controls per total specimen batch number required by the Michigan contract and/or CAP?	Michele	Complete	CAP requires 10% of the batch to be controls (not sure about the MI contract). We run two sets of controls (6 – 8) per 40 samples, so this requirement is met.
3. What are the acceptance criteria for each QC control within the batch?	Michele	Complete	Generally within 15% of target value, and two of three positive controls per set must pass. If they do not pass, samples with positive results must be repeated. Specific criteria are listed in the individual SOPs and the LCMSMS Quality Control procedure.
4. Are certifiers trained prior to performing review and release of results? Is that training documented in an employee file?	Michele	Complete	Yes and yes.
5. Was the Director of the lab certified to release results? Is there a document that shows her approval by the laboratory to release results?	Michele		Shannon will have to check the hardcopy of my file but I should be certified to release results. I have participated in PT surveys as well. (I did not train or sign off on SR that I recall).

6. Does the lab report results electronically and how is it done?	Courtney	Complete	Insert overview of Aversys here, pull from an RFP.
7. Does the lab use an information management system (LIMS)?	Courtney	Complete	Aversys, see the response the above question.
8. Does the LIMS perform audit tracking for critical areas of results certification and reporting?	Michele	Complete	Yes – we can check the DI log to see how results are received into the database and if they are modified and by who.
9. Concise description of how specimens received under the Michigan contract are received and tested at the laboratory. To include accessioning, screening, confirmation, certifying and reporting results back to the client.	Courtney	Complete	Does the COC description cover this scope?

SOP INFORMATION (required prior to the inspection audit). Need highlighted excerpts with the title of the SOP for the following:

Question	Owner	Status	Response
1. SOP excerpt that describes the acceptance criteria for each QC and specimens released by the certifier for both the screening and confirmation assays.	Michele	Complete	08 – IA Testing 11 – LCMSMS QC 18 – OF Confirmation
2. SOP excerpt that describes training required for all certifiers.	Michele	Complete	03 – Personnel and Training Link to all training presentations here (Teams): LCMSMS Training
3. Immunoassay screening SOP pertains to specimens reported under the Michigan contract.	Michele	Complete	08 – IA Testing
4. SOP Reporting section excerpt that pertains to specimens reported under the Michigan contract.	Michele	Complete	24 – Data Review and Reporting11 – LCMSMS QC
5. List of all SOP changes made after November 3rd, 2020.	Michele	Complete	Archived SOPs Link to Archive folder in the Lab Manual folder on Teams.

6. SOP description of action to be taken upon a control failure.	Michele	Complete	11- LCMSMS QC
7. SOP excerpt that describes partial batch acceptance if applicable.	Michele	Complete	11 – LCMSMS QC
8. SOP section that describes when it is allowed for the reinjection of QC and specimens.	Michele	Complete	11 – LCMSMS QC
9. SOP description of lab allowance for manual integration of controls and specimens?	Michele	Complete	11 – LCMSMS QC
10. SOP description of lab allowance for reintegration of the batch specimens?	Michele	Complete	11 – LCMSMS QC

LABORATORY INFORMATION (required prior to the inspection audit)

Question	Owner	Status	Response
1. Document package for a specimen that is sent to court for trial prior to September 14, 2020, and after November 3rd, 2020.	Courtney		Ask Traci at legal@averhealth.com for samples.
2. All internal notes, documentation of training, or memorandums for the record that describe control failures and how to correct the failures.	Michele	Complete	2021 LCMSMS BATCH PREP LOGS.xlsx (sharepoint.com) 2022 LCMSMS Batch Prep Logs.xlsx (sharepoint.com) Corrective action and training documents uploaded to Teams. Also see link to LCMSMS Training under SOPs #2 above.
3. Listing of personnel for accessioning, screening, confirmation, and certifiers.	Michele	Complete	Uploaded to Teams.

AUDIT REQUIREMENTS (required during the inspection audit)

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3. CAP - FDT PT testing data, Inspection reports, and corrective actions from September 14, 2020, to current date.

MG: Found here 05- Proficiency Testing

4. Control performance data during the inspection from September 14, 2020, to current date.

MG: Found here - 07- Levy Jennings

5. Complete set of SOPs.

MG: Found here:
https://avertest.sharepoint.com/:f:/s/LabTest/EpzjgXijV2pDm5ni77zwhmEBmCbNJWIS-1Pm8YGGGS6muw?e=SnSWGw

6. Former directors CV or resume and training file.

MG: HR would have.